DAVID Y. IGE
GOVERNOR OF HAWAII

VIRGINIA PRESSLER, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
STATE LABORATORIES DIVISION
2725 WAIMANO HOME ROAD
PEARL CITY, HAWAII 96782-1496

In reply, please refer to:
File: SLD/ADMIN

September 18, 2017

The Department of Health, State Laboratories Division is soliciting for bids for the services of an a nationally and internationally-recognized accrediting body for International Standard ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories" that has undergone multiple, rigorous, peer evaluations and been found to meet or exceed the requirements as set forth in ISO/IEC 17011 since the inception of these requirements.

I. Accreditation Services

The accrediting body must meet the following at the time of solicitation:

- Demonstrate capability of assisting the State Laboratories Division (SLD), Laboratory Preparedness and Response Program (LPRP) in achieving accreditation in microbiology by providing experienced staff to assess the LPRP; provide materials with an explanation about the process, and, a contact person to address LPRP questions, allowing SLD/LPRP quick and easy access to assistance and support when needed.

- Demonstrate capability to provide a full range of comprehensive laboratory and laboratory related accreditation services and training.

- Provide proof of recognition and/or membership with the Inter-American Accreditation Cooperation (IAAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC), the International Laboratory Accreditation Cooperation (ILAC), and the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA).

- Shall have a minimum of five (5) years in accreditation business, and two to five (2-5) years of experience providing accreditation to Food Microbiology testing laboratories.

- Describe the process by which the Contractor accredits laboratories (e.g. fields of study, test methods, technology, or other).

- Have tools and training available to assist with the basic needs of achieving, implementing, and maintaining the ISO/17025:2005 accreditation.

- Have a comprehensive training program available describing the resources, timeline, and materials needed to assist the LPRP Food Emergency Response Network (FERN) Microbiologist, management, and quality staff in the accreditation process. The LPRP shall be allowed to duplicate and distribute the comprehensive training program and materials without additional charge, provided all copyrights are not infringed, to additional SLD staff that are identified as needing the information (e.g. staff transfers, new staff).

- Provide information on how assessors are selected.

- Have assessors that meet a minimum of ten years of experience in their selected fields.

- Have assessors that meet minimum requirements for training, experience and certification and attend training in auditing and the interpretation of the standard to which they are assessing.

- Have rigorous and regular oversight over the assessors, resulting in the highest quality of assessment for our accredited facilities.

- Provide a list of resources (e.g. guidance documents on specific pieces of the standard (interpretation), free webinars, or other support (technical support)) in gaining and maintaining accreditation to the LPRP at no additional cost.

- Disclose any program specific requirements that are in addition to the basic standard for the ISO 17025 accreditation process, and provide updates as they occur.

- Provide a fee structure for the initial application process.

- Provide a fee structure for continuing accreditation, once achieved by the LPRP.

- Provide a fee structure for the addition of fields of study, test methods, technology, or other based on how the Contractor accredits laboratories.

- Provide a list of additional consultation services offered, if applicable, which will be an option for the LPRP to consider.

- Provide a copy of their measurement of uncertainty policy.

- Provide a copy of their proficiency sample policy.

- Provide an example inspection schedule, including a pre-accreditation inspection.

Tasks

The Contractor shall:

- Provide additional tools and training at the LPRP's request as needed at the pre-negotiated rates established through the Contract for onsite and/or offsite training.

- Provide technical support for the ISO 17025 training, application, and accreditation process Monday through Friday as requested by the LPRP, excluding federal and state holidays. Support shall be offered via multi-forms of communication to include at a minimum:

  Toll-free telephone line, please specify coverage times; and E-mail.

- Provide access, at all times, to a secure but free web portal allowing LPRP to upload documents that need to be provided during the accreditation process.
- Provide n easily accessible place to check on the status of SLD's assessment, and to upload additional information or respond to inquiries as well as a print ready copy of SLD's Scope of Accreditation and Certificate.

The Contractor shall provide a Point of Contact who shall, at a minimum:

- Serve as a primary day-to-day contact with the LPRP

- Ensure all necessary components are completed during the application process and subsequent inspection.

- Provide or ensure technical support for questions related to accreditation; and

- Designate an alternate contact for when the Point of Contact is unavailable.

- Provide guidance on pre-inspection and inspection cycles and processes, including the application process.

Requirements for the Contractor/Assessor

Security and Safety Requirements

- The LPRP is a secure building. The Contractor shall ensure that all employees and subcontractors are aware of the need to abide by the LPRP's security requirements.

- All Contractor employees and subcontractors shall be required to check in at the security desk and obtain a visitor badge,

- Shall be escorted at all times while in the building,

- Shall abide by the LPRP's current Personal Protective Equipment Policy when entering LPRP areas, and

- Shall abide by any additional security or safety items as relevant to the inspection of the LPRP.

- The LPRP performs methods with confidential analyte lists and the following security requirements are required.

- After presenting a confidentiality statement that indicates the content of the LPRP Procedure Manual is confidential and should not be released to a third party, the assessor(s) \will be able to review the analyte list while on-site; and

- Once the LPRP has achieved accreditation, the list of confidential analytes shall not be posted in any medium by the accreditation body.

Deliverables

The Contractor shall submit to the SLD-LPRP:

- The background on the inspectors assigned to the LPRP and on their inspection experience.

- An inspection schedule, including a pre-accreditation inspection, once an application has been submitted.

- Inspections within the required timeframes, once the application for accreditation is submitted.

- The inspection cycle once accreditation has been achieved.

- Provide an updated plan and timelines for any consultation (optional), pre-inspection, and initial inspection which both parties agree upon.

- Submit a current and valid Certificate of Insurance exactly as listed in the Special Terms and Conditions, including all special language, within ten (10) days of Contract award. A Purchase Order will not be provided to begin services without valid insurance.

Notices, Correspondence and Reports

Notices, correspondence, reports and invoices from the Contractor to SLD-LPRP shall be sent to: Ms. Elsie Cristobal and Ms. Rebecca H. Sciulli, M.S., M.T., R.B.P., at the following address:

Hawaii State Laboratories Division, 2725 Waimano Home Road, Pearl City, HI 96782
Phone (808)-453-5990 for Ms. Cristobal and (808)-453-5993 for Ms. Sciulli

II. **SCHEDULE**

The State Laboratories Division building opened in 1995 and operates during the hours of 7:45 A.M. to 4:30 P.M. Monday to Friday and is closed on the weekends and State holidays.

Please submit your price quotation by 12pm (Hawaii time), **October 3, 2017** on HIePRO. Award will be made to the lowest responsive, responsible offer. The offeror must be able to produce a Certificate of Vendor Compliance at the time of award and for final payment.

For information on the Certificate of Vendor Compliance, please refer to the SPO website, www.spo.hawaii.gov.

III. Criteria by which the "best value" to the state will be determined:

If all criteria mentioned above are met, the responsive, responsible offer will be determined by the lowest bid price for the unit

- Bidders must be "Compliant" with Hawaii Compliance Express (HCE) at noon (Hawaii time), "date of the award**", October 3, 2017.**

OTHER CONDITIONS:

- **Price shall include all applicable taxes and fees. HIePRO may charge transaction fees that the awarded bidder shall be responsible for paying.**

If you have any questions or require more information, please contact Ms. Rebecca Sciulli at (e-mail: **rebecca.sciulli@doh.hawaii.gov** /phone: 808-453-5993).